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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,173	07/09/2004	Henryk Struszczyk	16497.117	6041

57360 7590 11/20/2008

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EXAMINER	
WHITE, EVERETT NMN	
ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
11/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,173	STRUSZCZYK ET AL.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *10-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/26/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I, Claims 1-9, in the reply filed on August 7, 2008 is acknowledged.

2. The response to the restriction requirement filed August 7, 2008 and amendment filed December 20, 2007 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Claims 1, 2, 4, 9, 10, 21 and 33 have been amended;
(B) Comments regarding Office Action have been provided drawn to:

(I) 103(a) rejection, rendered moot by new ground of rejection over newly cited US Patent.

3. Claims 1-42 are pending in the case. Claims 10-42 are withdrawn from consideration as being directed to non-elected inventions.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 4, lines 4 and 5, the phrase "average polymerization degree" should be changed to - - average molecular weight - - since the unit (10 kD) for the numerical value of the phrase suggests a molecular weight value rather than a polymerization degree. Claims 5-9 are rejected for the same reason since these claims are dependent from Claim 4.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsuhiko (JP Publication No. 06-237712, newly cited) in view of Kawashima et al (US Patent No. 6,451,351, newly cited) or Struszczyk et al (US Patent No. 5,554,445, already of record).

Applicant claims a chitosan-calcium (II) complex consisting essentially of: a gel agent consisting essentially of a chitosan salt, wherein said complex contains ≥ 0.5 wt% chitosan having an average molecular weight ≥ 10 kD, a polydispersity ≥ 2.0, deacetylation degree ≥ 65% and wherein said complex has a water retention value ≥ 300%, pH ≤ 6.9 and calcium (II) ions bound to the chitosan at a content ≥ 0.1 wt% relative to chitosan. Applicants also claim a method to produce a chitosan-calcium

complex from a gel of a chitosan salt comprising the steps of: (a) providing a suspension containing ≥ 0.5 wt % chitosan gel, said gel agent having an average molecular weight ≥ 10 kD, a polydispersity ≥ 2.0, deacetylation degree ≥ 65%; and b) mixing said chitosan gel agent with ≥ 0.1 wt% calcium (II) salt to form said complex; wherein said complex has a water retention value ≥ 300% and a pH ≤ 6.9, said complex consisting essentially of chitosan and calcium.

The Katsuhiko publication discloses a chitosan gel which is produced by adding chitosan powder, an aqueous solution of an organic acid and a calcium salt to water, mixing the product and left standing the chitosan solution at room temperature to 70°C for 1-30 hours to effect the swelling of the gel. This description of the process in the Katsuhiko publication suggests preparation of a chitosan-calcium complex gel.

The instantly claimed chitosan-calcium (II) complex differs from the Katsuhiko publication by specifying the various properties of the gel agent, which include the gel agent consisting essentially of a chitosan salt, wherein said complex contains ≥ 0.5 wt% chitosan having an average molecular weight ≥ 10 kD, a polydispersity ≥ 2.0, deacetylation degree ≥ 65% and wherein said complex has a water retention value ≥ 300%, pH ≤ 6.9 and calcium (II) ions bound to the chitosan at a content ≥ 0.1 wt% relative to chitosan.

However, the use of chitosan having such properties in the preparation of gels is well known in the art. See the Kawashima et al patent wherein a method for preparing gel with calcium salts of organic acids is disclosed, wherein chitosan may be used which has a degree of deacetylation of 60% or more and an average molecular weight up to 400,000 Daltons (see column 2, 6th paragraph). See column 3, lines 7 to 10, wherein the pH of the reaction system for preparation of the gels preferably ranges from acidic to neutral pH, which embraces the pH range recited in the instant claims.

The Struszczyk et al patent is also cited to show that the properties of chitosan recited in the claims are known in the art. See Example 1 of the Struszczyk et al patent wherein microcrystalline chitosan is characterized as having an average molecular weight of 78000, deacetylation degree of 72%, and water retention value of 1240%.

One of ordinary skill in this art would be motivated to combine the teachings of the Katsuhiko publication with the teachings of the Kawashima et al and Struszczyk et al patents since each of the patents disclose chitosan product being used in the preparation of gels or liquid dispersions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the chitosan product used to prepare the chitosan-gel of the Katsuhiko publication with a chitosan having specific properties in view of the recognition in the art, as evidenced by the Kawashima et al and Struszczyk et al patent, that chitosan is an effective ingredient for stabilizing gel complexes.

Summary

8. Claims 1-9 are rejected; Claims 10-42 are withdrawn from consideration as being directed to non-elected inventions.

Reply to Final Must Include Cancellation of Claims Non-elected with Traverse

9. This application contains Claims 10-42 drawn to an invention nonelected without traverse in the reply filed on August 7, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

10. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on October 26, 2007 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Everett White/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623